52. (Amended) The isolated nucleic acid of claims [48] 49, 50, or [to]51, wherein the nucleic acid is cDNA or RNA.

D1

53. (Amended) A composition comprising the isolated nucleic acid of claims [48] 49, 50, or [to]51 and a carrier.

55. (Amended) A vector comprising the isolated nucleic acid of claims [48] 49, 50, or [to]51.

D2

56. (Amended) An isolated host cell comprising the isolated nucleic acid of claims [48] 49, 50, or [to]51.

Please add new claims 59 to 61:

59. (New) The vector of claim 55, wherein the vector is a pharmaceutically acceptable vector.

D3

60. (New) A composition comprising the vector of claim 59 and a carrier.

61. (New) The composition of claim 60, wherein the carrier is a pharmaceutically acceptable carrier.

II. REMARKS

Claims 35 to 58 are pending. Claims 39-42, 44-46 and 58 have been withdrawn from examination as a result of a request for restriction. Claims 35 to 38, 43 and 47 to 57 were examined. These claims have been examined and stand variously rejected under 37 CFR 1.75 (c), 35 U.S.C. § 101, 35 U.S.C. § 112, first paragraph, and § 102(a). Claim 58 (method of modulating cellular function by the CD40 in a cell) has been withdrawn from consideration as the result of a requirement for restriction. By this Amendment, this claim has been now been canceled without prejudice to Applicant's right to pursue prosecution of this claim in a later filed continuation or divisional application. Claims 35 to 38, 43, 47, and 48 have been canceled. The cancellation of these claims and the addition of new claims 59 to 61 are not intended to be a dedication to the public of the subject matter of the originally filed claims.

By amendment herein, claims 52, 53, 55 and 56 have been amended. Support for the amendments can be found in the claims and specification as originally filed. These amendments have been made to clarify the invention and to advance prosecution and are not intended to be a dedication to the public of the claims as previously presented. New claim 59 is supported in the specification at page 16, line 25 to page 17, line 9. New claims 60 to 61 are supported at page 23, line 30 to page 24, line 5. Further support for new claims 59 to 61 is found at page 28, line 34 through page 29, line 10. No new matter has been added as a result of these amendments and entry thereof is respectfully requested. Claims 49 to 57 and 59 to 61 are presently under examination.

In view of the preceding amendments and the following remarks, Applicant respectfully requests reconsideration and withdrawal of the outstanding objections and rejections.

Specification

Claims 52, 53, 55, and 56 stand objected to under 37 CFR 1.75 (c) as allegedly being in improper form because a multiple dependent claim should refer to other claims in the alternative only. Claims 52, 53, 55 and 56 have been amended to meet this requirement. In view of these amendments, Applicant respectfully requests withdrawal of this rejection.

35 U.S.C. § 101

Claims 38 and 56 stand objected to under 35 U.S.C. § 101 because the claimed invention was allegedly directed to non-statutory subject matter. Claims 38 and 56 were amended as per Examiner's suggestion in order to obviate this rejection. Because the Examiner alleged "[a] host cell" encompassed a human organism, Applicant amended the claims to "an isolated host cell." In view of these amendments, Applicant respectfully requests withdrawal of this rejection.

35 U.S.C. § 112, First Paragraph

Claims 35 to 38, 43, 47 to 50 and 52-57 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventor had possession of the claimed invention. Allegedly, no proper antecedent basis nor conception in context for the element "wherein the carrier is a solid support" is apparent in the specification. In addition, the Office alleges that no proper antecedent basis nor conception in context for a nucleic acid "that is at least 90%

homologous" *and* encodes a protein "*comprising* amino acids 297 to 567 as shown in SEQ ID NO:2" is disclosed in the specification. The Office further alleges that the specification provides a written description of a single species of a nucleic acid encoding the CD40 binding protein: SEQ ID NO:1. The Office alleges that no other species of CD40bp are disclosed within the instant specification.

Claims 35 to 38, 43, 47 to 50 and 52 to 57 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being enabled by the specification. The Office states that the specification describes a nucleic acid comprising SEQ ID NO:1 or a nucleic acid encoding the human CD40 binding protein of SEQ ID NO:2. In brief, it is alleged that the specification fails to set forth sufficient structural and functional characteristics to support breadth of the claims. For example, the element of a nucleic acid "that is at least 90 % homologous" *and* encodes a protein "*comprising* amino acids 297 to 567 as shown in SEQ ID NO:2" is allegedly not enabled because the specification does not provide guidance as to what critical amino acids are required for any generic and active encoded CD40bp protein, or fragments thereof.

For the reasons provided below, Applicant traverses.

With respect to the element "wherein the carrier is a solid support" of claim 54, Applicant has disclosed the invention in the specification, Figures 3D and 3E, and Experiment V of the application. Importantly, the specification states that the invention provides compositions containing "<u>any of the above-mentioned</u> proteins, muteins, polypeptides or <u>fragments</u> thereof, and an acceptable solid or liquid carrier." *See* page 23, lines 25 to 27 (emphasis added). With respect to nucleic acids, the specification discloses that nucleic acid fragments of the sequence of SEQ ID NO:1 and its equivalents are useful as probes. *See* page 13, lines 4 to 7. Additionally, the specification discloses that "nucleic acid fragments of at least 10 nucleotides are useful as hybridization probes" (*see* page 13, lines 16 to 17) and "[i]solated nucleic acid fragments also are useful to generate novel peptides (*see* page 13, lines 18-19)." The specification defines a solid phase carrier as a group containing nylon, natural and modified celluloses, polyacrylamides and agaroses. *See* page 9, lines 28-31. In Experiment V, the nucleic acid was hybridized and transferred utilizing gels. Specifically, the electrophoresis utilized agarose gel. *See* page 36, line 15-16. Figures 3D and 3E show expression of CD40bp transcript which was accomplished using

gels as solid support. Thus, the element of "a solid support carrier" attached to the nucleic acid has adequate antecedent basis as disclosed within the specification.

Applicant has canceled claim 48 which was for a nucleic acid "that is at least 90% homologous" *and* encodes a protein "*comprising* amino acids 297 to 567 as shown in SEQ ID NO:2." Applicant has also canceled claim 35, which claimed a "purified mammalian protein having the ability to bind the cytoplasmic region of CD40 receptor" and, accordingly, claims 36 to 38, 43 and 47 which depended from claim 35 were also canceled.

With respect to the generation of nucleic acid fragments encoding CDbp polypeptides that are structurally and functionally uncharacterized, Applicant has identified that the C-terminus is required for binding to CD40 and provided a simple *in vitro* screen for CD40 binding. *See* page 38, lines 1 to 5. With respect to the essential amino acids necessary to maintain the function of CDbp polypeptides, Applicant has identified these in the specification at page 37, line 10 through page 38, line 10. Applicant has also provided, in one embodiment, the full amino acid sequence for CD40bp. This information fully enables the claim to "equivalent nucleic acids" which have a sequence homologous to SEQ ID NO:1 of at least 90% because, one of skill in the art, using Applicant's disclosure, can make numerous polypeptide fragments from these nucleic acid sequences and assay for CD40 binding specificity. Additionally, the nucleic acid sequence can be found by using reverse translation of the amino acid sequence and homology based computer-assisted searches. *See* page 36, line 17. The disclosure need not teach, and preferably omits, what is well known in the art. *Hybritech v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). Indeed, other investigators have made such polypeptide fragments from nucleic sequences that fall within the scope of Applicant's claims (*See* prior art cited against the claims, below).

As Applicant states on page 11, lines 3 to 5, the nucleic acid sequence of SEQ ID NO: 1 is only "one aspect of this invention." Applicant further discloses on page 13 at lines 4 to 7 that "[f]ragments of the sequence shown in Figure 5 and its equivalents are useful as probes to identify transcripts of the protein which may or may not be present." Additionally, Applicant discloses the utility of his invention as a hybridization probe or in the generation of novel peptides. *See* page 13, lines 16 to 21. Applicant has provided the nucleic acid sequence for the invention along with the necessary isolation techniques in order to be able to make and utilize

nucleic acids which are claimed. It has been held that the specification was enabling where: 1) "there was considerable direction and guidance" in the specification; 2) there was "a high level of skill in the art at the time the application was filed"; and 3) "all of the methods needed to practice the invention were well known. *In re Wands*, 858 F.2d 731, 740, 8 USPQ2d 1400, 1406 (Fed. Cir. 1988).

In view of the foregoing amendments and remarks, withdrawal of these rejections is respectfully requested.

35 U.S.C. § 102

Claims 35 to 38, 43, 47 to 53 and 55 to 57 stand rejected under 35 U.S.C. § 102 (a) as allegedly anticipated by Hu et al., Sato et al., Mosialos et al., or Cheng et al.

Hu et al. is Applicant's own publication and, thus, cannot be used as prior art against the claimed invention under 35 U.S.C. § 102 or § 103. In support of the position that the publication is Applicant's own, attached hereto is an "In re Katz" declaration under 37 C.F.R. § 1.132, which was filed in the parent application to obviate the rejection over the same cited reference. In view of the submission of this declaration, removal of the rejection of the claims over Hu et al. is respectfully requested.

Applicant also will submit a declaration under 37 C.F.R. § 1.131 showing a conception and reduction to practice of the invention prior to the publication of Sato et al., Mosialos et al. and Cheng et al. In view of the submission of this declaration, removal of the rejection of the claims as allegedly anticipated by these references is respectfully requested.

Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement has also been filed on this date for this application. This Supplemental Information Disclosure Statement is provided in response to Examiner's assertion that the copy of a reference listed on a PTO Form-1149 was not found.

III. CONCLUSION

If a telephone interview would advance prosecution of the subject application, the Examiner is invited to telephone the undersigned at the number provided below.

In the unlikely event that the transmittal letter is separated from this document and/or the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-0974**, referencing attorney docket no. 128019201702. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: February 20, 2001

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